

REMARKS

This amendment is response to the Office Action of July 8, 2010. In the application Claims 44-52 are pending. In the current Office Action, Claims 44-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Carter, U.S. Patent No. 6,478,791 in view of Geitz, U.S. Patent No. 6,592,596. Reconsideration is respectfully requested.

Rejection Under 35 U.S.C. §103(a)

Claim 44 stands rejected as obvious over a combination of three prior art references. Carter, the primary reference cited against Claim 44, discloses a "pivotal plication probe" with a pair of arms 52 that pivot relative to a shaft 42. [Col. 8, ll. 35 – 37]. The arms cause tissue fold 22 to form "in the desired direction." [Col. 8, l. 41]. As shown below, that direction is *away* from and outside the device

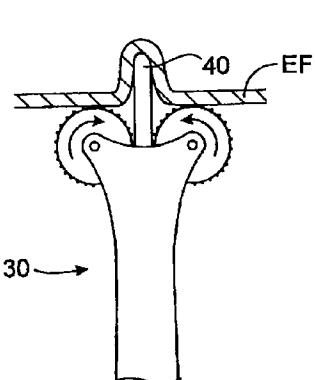


FIG. 8C

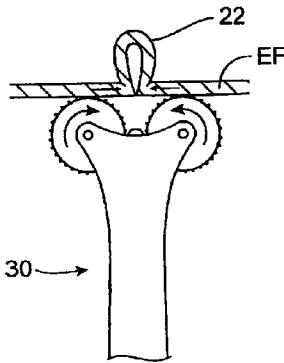


FIG. 8E

Note that the roughed edges of the arms 52 serve the same purpose as the jagged surface of the wheels, and rods 54 operate exactly like rod 40 above to push the tissue away from the device so as to create the fold.

Claim 44 includes the limitation of "adhering tissue from the region *within* each of the first and second acquisition members." The Office Action submits that Carter teaches the step of "adhering tissue *with* the first and second acquisition members." This is not

what the claimed step requires. The claimed step calls for the tissue to be adhered *within*, not *with*, the acquisition members. It is clear that Carter fails to teach the recited limitation, and the Office Action attempted to change the claim language rather than show that the claimed invention was taught by the prior art. Because the Office Action failed to show where the prior art taught the step of "adhering tissue from the region within each of the first and second acquisition members," the rejection must be withdrawn.

Claim 44 also calls for the step of compressing the adhered tissue between the first and second acquisition members. Applicant respectfully submits that this step is not shown in the Carter disclosure as submitted by the Office Action. If one examines the operation of the Carter device, no tissue is ever "compressed" by the acquisition members. Rather, a fold is created by moving tissue's surface between the two arms until it folds outward. At no point is the tissue compressed, nor could it be compressed using the Carter device as taught by Carter. This misunderstanding of the operation of the Carter device has led to an incorrect statement about what is taught by Carter, and the rejection cannot stand. If the rejection is maintained, Applicant respectfully requests that a non-final office action be entered explaining where the tissue is "compressed" in the Carter device using arms 52 as contended by the Office Action, as opposed to arms using the abraded surface to simply move the tissue's surface together to create a fold. Absent such teaching, the rejection of Claim 44 is incorrect and is rightfully withdrawn.

The Office Action further attempts to justify the proposed combination of Carter with Geitz, a device that is used to staple the fundus to the GEJ. The Geitz' device is a cup-shaped device that surrounds the GEJ and uses staples to lengthen the esophagus. One of ordinary skill in the art, in possession of both Geitz and Carter, would recognize the Carter's device would be wholly unsuitable for the application of Geitz, and vice versa. Moreover, because Carter's device must be directed straight ahead since it teaches no pivoting device (now would one be needed for the application it was intended), there is nothing in these references that would suggest Carter would be suitable for a

transesophageal approach. In fact, one of ordinary skill in the art would easily recognize that Carter would be of little use to achieve either the goals of Carter or the goals of Geitz using a transesophageal approach, since it could not be used to lengthen the esophagus and could not be used to form a fold in the stomach wall since it cannot pivot or otherwise approach the stomach wall.

The Office Action cites KSR Int'l Co. v. Teleflex for the proposition that use of a known technique to improve a similar device will yield predictable results. [O.A., p. 4] But the Office Action fails to explain how the device of Carter "improves" the device of Geitz. Applicant respectfully submits that not only does it fail to "improve" the device of Geitz, but in fact it cannot even do what Geitz' device can do. Thus, the rejection is based on a faulty premise, and thus KSR's holding does not support the Office Action's rejection of Claim 44.

The Office Action's further attempt to modify the proposed Geitz/Carter combination to add the teachings of Badie are even more incredible. The Office Action argues that Badie, which is directed to forceps, teaches suction and that, therefore, it would have been obvious to modify the device of Carter to have a suction force "as it would better secure the tissues within the tissue acquiring members." First, Carter teaches that the tissue folds outward, or *away* from the acquisition members. Vacuum would work against this objective and draw the tissue toward the acquisition members. While this is a feature of the present invention, the Office Action must look to what was known before Applicant's disclosure and not rely on Applicant's disclosure to provide a basis for the combination. Since there is no logical grounds to be found in the cited prior art for applying vacuum to Carter, the proposed modification using Badie's forceps are invalid.

The newly enacted Examination Guidelines, Federal Register Vol. 75, September 1, 2010, at page 53646 is illustrative of the requirements for showing obviousness:

Even though the components are known, the combining step is technically feasible, and the result is predictable, the claimed invention may nevertheless be nonobvious when the combining step involves such additional effort that no one of ordinary skill would have recognized reason to do so. When a combination invention involves additional complexity as compared with the prior art, the invention may be non-obvious unless the examiner can articulate a reason for including the added features or steps. This is so even when the claimed invention could be readily implemented.

Here, the Carter invention is used to treat incontinence by treating the endopelvic fascia. There is no basis for adding the complexity of a suction system to the device, which would add both cost and require a complete redesign for no apparent benefit. The Office Action provides no evidence that suction would "better secure the tissues" than the existing mode of adherence, and there is nothing in prior art that would support this theory. Further, the Office Action's point that suction would provide irrigation is wholly irrelevant to the claimed invention, for an irrigation port would not meet the claim limitation of drawing *tissue* into each of the first and second acquisition members. Irrigation ports would avoid having tissue drawn in, as that would defeat the purpose of the irrigation port. Thus, there is simply no basis for adding the teachings of Badie to the teachings of Carter absent impermissible hindsight, and the Office Action failed to show how the device of Carter would be *improved* by the proposed modification.

In view of the foregoing, it is respectfully submitted that the rejections as pending cannot be sustained and must be withdrawn. Claims 44 – 52 are now asserted to be in allowable condition and early notification of same is respectfully requested. If the Examiner believes that a telephone conference will further the prosecution of this application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is authorized to charge any deficiencies or fees in connection with this amendment to Deposit Account No. 06-2425.

Respectfully submitted,
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